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Manuscripts

Development and Utility of Quality Metrics for Ambulatory Pediatric Cardiology in Kawasaki Disease

Short abbreviated title:
Quality Metrics for Ambulatory Pediatric Cardiology in Kawasaki Disease

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Abbreviations: American Heart Association (AHA), American College of Cardiology
(ACC), Adult Congenital and Pediatric Cardiology Section (ACPC), Kawasaki Disease
(KD),

While the final metrics were published in a previous article (J Am Coll Cardiol. 2017 Feb
7;69(5):541-555. doi: 10.1016/j.jacc.2016.11.043), this article dives in detail to explain
the development and early stages of the Kawasaki disease ambulatory metrics. For
pediatricians considering developing metrics related to the care of children in the
ambulatory setting, this article explains in details the organization of a team, selection of
metrics and the different development milestones. This paper is not under consideration
for publication elsewhere, and all authors have read and approved the manuscript. This
submission is with the full knowledge and approval of the listed coauthors.

Abstract

The Adult Congenital and Pediatric Cardiology Section (ACPC) of the American College of Cardiology sought to develop quality indicators/metrics for ambulatory pediatric cardiology practice. The objective of this study was to report the creation of metrics for patients with Kawasaki Disease (KD). Over a period of five months, 12 pediatric cardiologists developed 24 quality metrics based on the most relevant statements, guidelines, and research studies pertaining to KD. Of the 24 metrics, the eight metrics deemed the most important, feasible and valid were sent on to the ACPC for consideration. Seven of the eight metrics were approved using the RAND method by an expert panel. All seven metrics approved by ACPC council were accepted by ACPC membership after an “open comments” process. They have been disseminated to the pediatric cardiology community for implementation by the ACPC Quality Network™.

INTRODUCTION

Kawasaki disease (KD) is the leading acquired heart disease in developed countries.¹ Without timely diagnosis and treatment, 25% of these children have coronary artery involvement. In 2004, the American Heart Association (AHA) and American Academy of Pediatrics jointly published a scientific statement on the diagnosis and management of KD,¹ which included recommendations for treatment in the acute phase and its long term management. The statement was revised in 2017.¹ Such statements are essential tools for clinical practice; they collect and analyze all published information, and recommend management strategies to practicing physicians to guide their care. They do not, however, evaluate compliance with recommendations or the quality of the care given by practitioners to identify areas of assessment or management that can be improved. Scientific statements and guidelines can be used to define benchmarks for care. Quality metrics derived from guidelines can be applied to record review to assess and promote quality of care. In this manner, metrics highlight a community's adherence to current best practices and promote quality improvement.

In 2012, the Adult Congenital and Pediatric Cardiology Section (ACPC) of the American College of Cardiology (ACC) sought to create quality metrics for ambulatory pediatric cardiology care. Within this initiative, KD was chosen as a specific area of practice for metric development, particularly because of the existence of the 2004 AHA Scientific Statement on Kawasaki disease noted above. Metric development was focused on ambulatory care provided to patients treated for KD by pediatric cardiologists following hospital discharge. This project was one of five that were undertaken under the auspices of ACPC and that recently were published as a group.³

This manuscript presents, in greater detail, the development of the KD metrics from their inception to implementation.

METHODS:

Work Process

The Kawasaki Disease metric development team consisted of 12 pediatric cardiologists from North America. Monthly conference calls and e-mail communications were used to survey team members for potential areas of focus for outpatient KD metrics. Key areas of focus included all disease phases of KD: the diagnosis of KD, its acute management (through 6-8 weeks follow up), and the long-term management of patients with coronary arterial involvement. Team members were then divided into subgroups of 2-3 cardiologists who wrote metrics related to a specific area of focus. Each subgroup evaluated the existing literature to help formalize the metric. The presentation of the quality metric included a description of the metric, the numerator, the denominator, the period of assessment, the data source, the rationale, the method of reporting, and challenges to its implementation.

Metrics were initially created, modified, and circulated to the full committee for review. Metrics that included inpatient care or data collection, or that were deemed too difficult to implement, were discarded. An Oversight Subcommittee (David Teitel, Michael Portman, and Jane Newburger) refined the eight final metrics (Table 1), and converted them into a uniform structure for submission to the ACPC expert panel. Using the RAND process to evaluate validity and feasibility,⁴ described in detail in an earlier

manuscript,³ the Expert Panel sent seven of the eight metrics to the Steering Committee for consideration. In turn, the Steering Committee sent those seven metrics out to all ACPC members for feedback. The comments received were then reviewed by the Steering Committee and the metrics were accepted, modified (if minor concerns) or rejected. Of the seven metrics sent by the Expert Panel to the Steering Committee, **all** were approved during the open comments process and finally approved by the ACPC council.

Utilization of **Existing Guidelines**

KD was unique among the pediatric ambulatory quality metric projects in having an AHA Scientific Statement to provide guidance for ambulatory care.^{1, 2} The 2004 AHA Statement were published before our metric project was undertaken and served as the basis for many of the developed metrics. For each metric, a citation from the 2004 AHA Statement was referenced in the clinical recommendation section of the metric. In addition, it was used to design the risk stratification that we incorporated into each metric, as noted above. Table 5 in the AHA Scientific Statement presents much of the information that was used in the creation of several of the metrics.¹

Recognizing that the 2004 Scientific Statement would be updated, we sought to choose metrics that were based upon the strongest levels of evidence in contemporary literature that would be considered in the new scientific statement. We also made the criteria for risk stratification based upon aneurysms as non-specific as possible (small, medium, etc., rather than specific dimensions), allowing for new variables such as z-

scores to be incorporated into the metric, and did not specify the type of stress testing technique to allow for emerging modalities..

In addition to the Scientific Statement, other guidelines were used in metric construction and justification. “Guidelines for Diagnosis and Management of Cardiovascular Sequelae in Kawasaki Disease,” developed by a joint working group of the Japanese Circulation Society,⁵ also informed many of our metrics, particularly those related to the long-term management of patients with coronary aneurysms. Since much of outpatient diagnostic activity relates to echocardiography, we referenced the guidelines developed by the American Society of Echocardiography for the performance of a pediatric echocardiogram.⁶ We referenced the 36th Bethesda Conference on Eligibility Recommendations for Competitive Athletes with Cardiovascular Abnormalities, which, in Task Force 2, discusses exercise limitations in patients with KD.⁷ These guidelines have also been updated recently, in a joint AHA and ACC Scientific Statement.⁸ Although we created one metric based on exercise limitations, it was not submitted. Lastly, because morbidity in KD is caused primarily by acute or chronic coronary artery disease, we referenced the NIH-commissioned “Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents”.⁹

Literature Reviewed

For each metric, we cited the specific statements within the various guidelines that justified adherence to the metric, as noted above. When the level of evidence was limited or there was no further corroborating data, we used other manuscripts, which

both pre-dated and post-dated the various guidelines, to form the rationale for our clinical recommendations. This was particularly necessary with regard to the use of echocardiography in following the disease process, and the categorization and treatment of coronary aneurysms, which is an evolving field. For example, Manlhiot described a classification system for coronary aneurysms based only on z-score,¹⁰ and Sugahara et al.¹¹ demonstrated the value of warfarin in preventing myocardial infarction in patients with giant aneurysms. The variability and cost-effectiveness of echocardiography in children with KD were considered in studies by Scott et al.¹² and Lowry et al.¹³, respectively.

Implementation of KD quality metrics

In early 2015, the ACC created a structure via which the quality metrics could be implemented. It is called ACPC Quality Network. Phase 1 (a pilot project of 3 sites) and Phase 2 (a “soft launch” with 13 sites) were undertaken in the second half of 2015 and the first half of 2016, respectively. The full launch was begun in the third quarter of 2016, after the ACC informed academic pediatric cardiology programs and private pediatric cardiology practices of the initiative. Those groups which decided to participate received all of the approved metrics and their quarterly data has been submitted since that time. Each center was assigned a unique alphabetical letter and their data is both presented individually and reported as an average for the metric in each quarterly report.

RESULTS

Key Decisions

When planning the development of the metrics, we chose to include all phases of the experience in the ambulatory pediatric cardiology practice, as well as each of the various risk classifications, focusing particularly on the high-risk patient with coronary aneurysms. We also sought to align the proportions of metrics relevant to each phase of illness with the corresponding relative time devoted to that illness phase in the outpatient cardiology office. Following our initial email conversations and phone conference, we defined eight potential metrics for diagnostic and acute management phase, and 12 for the late management phase, 10 of which focused on patients who had had aneurysms at some point during the disease. During later discussions, one early phase metric was added and one was split into two (one for low risk and one for higher risk patients), and two chronic phase metrics were added, leading to a total of 24 metrics.

In our creation of metrics for all phases of cardiac care for KD patients, we prioritized both feasibility (ease and reliability of data extraction from the medical record) and the importance of the metric to patient outcome. The study advisors were particularly helpful in considering feasibility, each having created quality metrics for adult congenital heart disease in the past.

Issues of data validity were particularly challenging for a variety of reasons. The AHA Scientific Statement that we were referencing at the outset of this project was published more than a decade ago. Not only has the treatment of KD evolved, but

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3 diagnostic tests have advanced; for example, stress evaluations are being done using a
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5 variety of new techniques, and advanced non-invasive imaging modalities (CTA, cMRA)
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7 have replaced cardiac catheterization in many centers. In addition, the definition of large
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9 and giant aneurysms was in flux at the time, and recent literature supports the use of z-
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11 score criteria to determine when anticoagulation should be added to anti-platelet
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13 therapy to prevent coronary thrombosis. Indeed, this approach has been adopted in the
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15 new Scientific Statement.³ Therefore, we focused on constructing quality metrics that
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17 were specific to important areas of evaluation and care throughout the course of KD in
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19 low and high risk patients while keeping the methodologies of risk stratification,
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21 investigation and care non-specific enough to allow the metrics to remain relevant as
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23 new statements and guidelines are published. We believe that this approach
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25 comprehensively interrogates the important components in the quality of outpatient KD
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27 care while being sufficiently general and evidence-based to maintain validity in face of
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29 new original research or updated guidelines.
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36 **Final Recommendations**

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39 The original metrics were discussed and revised in multiple venues, including
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41 conference calls with the entire team, individual email discussions, phone conversations
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43 of our oversight group, and email and phone conversations with the Steering Committee
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45 and Advisors. Our team finalized eight metrics and sent them through the Steering
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47 Committee to the Expert Panel for consideration (Table 1). Rating each metric on
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49 validity and feasibility using the RAND modified Delphi Expert Panel process,⁴ the Panel
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51 approved seven of the eight.
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In consideration of the eighth metric, the Expert Panel determined that data acquisition around discussion of preventative care in KD patients with aneurysms was problematic. It was unclear to the panel how one could reliably extract evidence from the chart that an appropriate discussion had been undertaken for many of the variables. Not only was the feasibility of data acquisition uncertain, but the validity of the measure was questioned. Both the validity and feasibility scores for this metric were lower than for all of the others, and the range of scores across the experts was much wider, indicating lack of consensus. Thus, this metric was not approved for further consideration.

The Panel sent seven metrics back to the Steering Committee, without edits. The Steering Committee then sent the metrics out to the members of ACPC for consideration for the “open comments” process. There were no major concerns expressed during the open comments period, and all seven metrics were voted upon by the ACPC council for final approval. The final seven metrics met our goal, by encompassing the delivery of ambulatory care through all phases of KD and focusing on long-term outpatient care for patients with coronary aneurysms.

Implementation of KD Quality Metrics

As noted above, the ACC invited all US pediatric cardiac programs and practices known to them to participate in the implementation of the ambulatory pediatric cardiology quality metrics via ACPC Quality Network. Figure 1 portrays the data acquired from the beginning of the full launch through the second quarter of 2017, for ACPC Quality Metric 14, the proportion of patients without aneurysms who had at least

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one echocardiogram within 3 weeks after being discharged from the hospital. The centers are able to review their own data across time periods, and compare their data with other centers and with the mean. With that information, they can determine where they need improvement and where they do not, develop strategies for improvement, and then determine the efficacy of those strategies.

DISCUSSION

We were able to develop seven KD ambulatory quality metrics by reviewing the existing literature that defined current best practices. The metrics were reviewed by experts in the field, who determined that the numerator and denominator of each metric could be ascertained, and that acquisition of data in the outpatient setting was both feasible and reliable. The metrics have since been disseminated by ACPC Quality Network, to afford pediatric cardiac programs the ability to evaluate their care, to compare that care to other programs, and to determine the efficacy of interventions aimed at improving their care. A Quality Network Collaborative National Quality Improvement project incorporating the KD metrics is under development and is expected to launch in early 2018.

Outpatient care of the KD patient is particularly suited to the use of quality metrics. In developing the outpatient KD metrics, we were mindful of several factors, including ease of data extraction from outpatient charts in diverse pediatric cardiology practice settings, the evolving nature of the care and evaluation of this patient population, the difficulty in defining a single standard with which to evaluate coronary

artery enlargement, and the existence of an outdated AHA Scientific Statement that was undergoing revision during our work. With increasing use of electronic medical records in the ambulatory setting, it should become easier to both extract the data needed to monitor compliance with these quality metrics and to use analytic tools to identify areas with opportunities for improvement. It is our hope that ambulatory quality metrics initiatives such as this one will encourage careful and comprehensive acquisition of data on the clinical care of KD patients, and will be used to compare that care to expected benchmarks.

Ambulatory metrics will only succeed in improving care if practicing pediatric cardiologists embrace the initiative and are willing participants. Barriers to this initiative remain the motivation of caregivers and inadequate systems to extract and analyze data in a timely and effective manner. Outreach and educational programs by the ACC, with the ability to grant Maintenance of Certification credit for adherence, will be seminal in inspiring the use of outpatient metrics for care of KD patients in pediatric cardiology practices. Finally, these quality measures must be updated systematically as new research further improves care for the KD patient, and as new guidelines are developed.

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For Peer Review

Figure Legends

Figure 1: Data acquired from participating centers since the full launch of the ACPC

Quality Network project for Quality Metric 14, the proportion of KD patients without aneurysms who had at least one echocardiogram within 3 weeks of discharge from hospital (used with permission of the ACC).

Table 1: Candidate Quality Metrics for Kawasaki Disease submitted to Steering Committee

Of the eight metrics sent, seven (**bold**) were approved by the Expert Panel. All were approved by the Steering Committee.

Author Contributions

David F. Teitel: team lead for the Kawasaki Disease Quality Metrics Group, wrote at least one metric and was the primary editor of at least one metric, reviewed and edited all of the metrics as part of the Oversight Subcommittee, communicated with the ACPC Quality Working Group, was the primary author of the manuscript.

Jane W. Newburger: wrote at least one metric and was the primary editor of at least one, reviewed and edited all of the metrics and was a primary editor of the manuscript as part of the Oversight Subcommittee.

Nicole Sutton: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Lloyd Y. Tani: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Ashraf S. Harahsheh: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Pei-Ni Jone: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Deborah J. Mensch: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality

Metrics Group, and reviewed and edited the manuscript.

Timothy Cotts: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Alex Davidson: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Nagib Dahdah: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Walter H. Johnson Jr: wrote at least one metric and was the primary editor of at least one, reviewed and edited the metrics as part of the Kawasaki Disease Quality Metrics Group, and reviewed and edited the manuscript.

Michael A. Portman: wrote at least one metric and was the primary editor of at least one, reviewed and edited all of the metrics and was a primary editor of the manuscript as part of the Oversight Subcommittee.

Table 1: Candidate Quality Metrics for Kawasaki Disease submitted to Steering Committee: Of the eight metrics sent, seven (**bold**) were approved by the Expert Panel. All were approved by the Steering Committee.

KAWASAKI DISEASE		
Candidate Metric	Numerator	Denominator
Complete Echo Evaluation of Coronary Arteries in KD	number of patients who undergo an echocardiogram with recording of all necessary structures and measurements	all patients diagnosed with KD seen during timeframe
Aspirin Therapy in Acute and Subacute Phases of KD	patients discharged after initial admission for KD who are on aspirin at 3-5 mg/kg during the first 6 weeks of their course	patients discharged after initial admission for KD <i>Excluded Populations:</i> <ul style="list-style-type: none">• Patients with G6PD deficiency• Other contraindications to aspirin (allergy, recent varicella vaccination)

<p>Appropriate Initial Outpatient Followup in KD Patients without Aneurysms</p>	<p>KD patients without aneurysms who have an echocardiogram performed within 3 weeks of hospital discharge</p>	<p>All KD patients found to have no aneurysms during hospital admission</p> <p><i>Excluded Populations:</i></p> <ul style="list-style-type: none"> • Patients at higher risk – persistent or recrudescent fever, or remain hospitalized >five days, or readmitted
<p>Appropriate Consideration and Evaluation of Fever in Acute and Subacute Phases of KD</p>	<p>KD patients who have assessment of fever post discharge at first cardiology outpatient visit</p>	<p>all KD patients seen in cardiology practice after hospital discharge</p> <p><i>Excluded Population:</i></p> <p>Patients whose first outpatient visit > 2 mos after discharge</p>
<p>Appropriate Care in Low Risk Patients (No Therapy or Restrictions) following Subacute Phase of KD</p>	<p>KD patients >8 weeks from disease onset with Risk Level I or II who are counseled that they do not need anti-platelet therapy or physical activity limitations</p>	<p>patients with KD >8 weeks from disease onset with Risk Level I or II</p> <p><i>Excluded Populations:</i></p> <ul style="list-style-type: none"> • Patients who do not return for followup in this timeframe

Appropriate Stress Evaluation of KD Patients with Coronary Artery Aneurysms	KD patients >10 years with coronary aneurysms who have undergone exercise stress testing (myocardial perfusion or echo) within 30 months of the current visit for small aneurysms or within 18 months for giant aneurysms	KD patients with current evidence of coronary aneurysms <i>Excluded Populations:</i> <ul style="list-style-type: none">Patients unable or decline to exercise
Appropriate Counseling re Myocardial Infarction in KD Patients with Giant Coronary Artery Aneurysms	KD patients with giant coronary aneurysms who have documentation of counseling regarding myocardial infarction within past 3 years	KD patients with history of giant coronary artery aneurysms

<p>Appropriate Discussion of Preventative Care in KD Patients with Aneurysms</p>	<p>KD patients >2 years of age with aneurysms and more than 1 year post onset of KD who have documentation of ≥ 3 of the following measures/counseling:</p> <ol style="list-style-type: none"> 1. Blood pressure 2. Lipid profile 3. Weight 4. BMI 5. Fasting glucose, hemoglobin A1C or fasting insulin 6. Family history of atherosclerotic heart disease 7. Avoidance of smoking 8. Avoidance of obesity 9. Exercise recommendations 10. Heart-healthy diet 11. Reproductive counseling 	<p>KD patients >2 years of age and more than one year post onset of KD who, at the time of evaluation, have coronary aneurysms</p>
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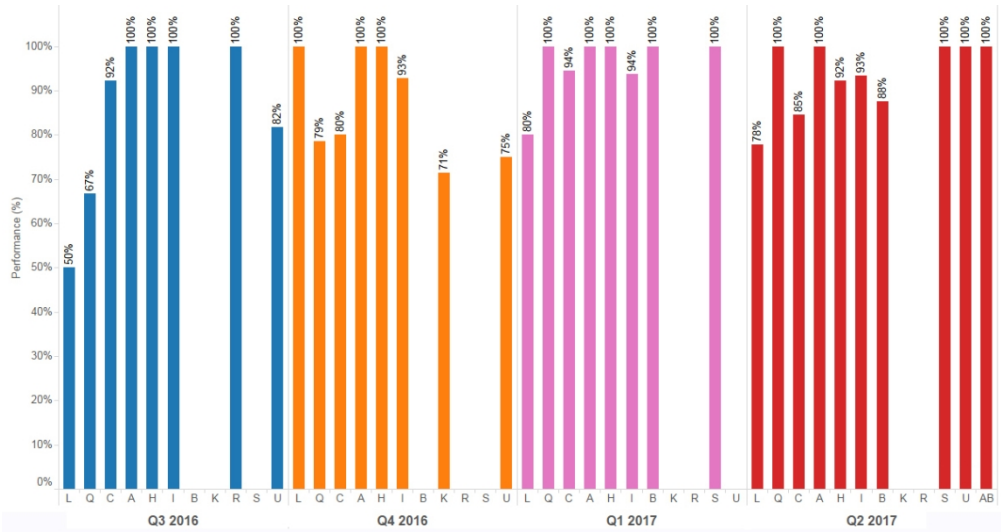


Figure 1: Data acquired from participating centers since the full launch of the ACPQ Quality Network project for Quality Metric 14, the proportion of KD patients without aneurysms who had at least one echocardiogram within 3 weeks of discharge from hospital (used with permission of the ACC).

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